4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0150]

Revocation of Two Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection and/or Diagnosis of COVID-19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to Bio-Rad Laboratories, Inc., for the Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit and to Applied DNA Sciences, Inc., for the Linea COVID-19 Assay Kit. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

DATES: The Authorization for the Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit is revoked as of April 15, 2022. The Authorization for the Linea COVID-19 Assay Kit is revoked as of April 20, 2022.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revocations may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the revocations.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993-0002, 240-402-8155 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108-276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On February 11, 2021, FDA issued an EUA to Bio-Rad Laboratories, Inc., for the Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on April 23, 2021 (86 FR 21749), as required by section 564(h)(1) of the FD&C Act. On May 13, 2020, FDA issued an EUA to Applied DNA Sciences, Inc. for the Linea COVID-19 Assay Kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on July 14, 2020 (85 FR 42407), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to the Authorizations were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. EUA Revocation Requests

In a request received by FDA on March 17, 2022, Bio-Rad Laboratories, Inc., requested revocation of, and on April 15, 2022, FDA revoked, the Authorization for the Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit. Because Bio-Rad Laboratories, Inc. notified FDA that it has ceased U.S. distribution of the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit,

has discontinued the assay, and requested FDA revoke the EUA for the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit, FDA determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on April 7, 2022, Applied DNA Sciences, Inc., requested revocation of, and on April 20, 2022, FDA revoked, the Authorization for the Linea COVID-19 Assay Kit. Because Applied DNA Sciences, Inc. notified FDA that it has decided to discontinue distribution of the Linea COVID-19 Assay Kit and requested FDA withdraw the EUA for the Linea COVID-19 Assay Kit, FDA determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at https://www.regulations.gov/.

IV. The Revocations

Having concluded that the criteria for revocation of the Authorizations under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA of Bio-Rad Laboratories, Inc., for the Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit, and Applied DNA Sciences, Inc., for the Linea COVID-19 Assay Kit. The revocations in their entirety follow and provide an explanation of the reasons for each revocation, as required by section 564(h)(1) of the FD&C Act.

U.S. FOOD & DRUG ADMINISTRATION

April 14, 2022

Elizabeth Platt EdD, MS, MBA
Sr. Director, Regulatory & Clinical Affairs | Americas
Bio-Rad Laboratories, Inc.
4000 Alfred Nobel Drive
Hercules, CA 92647
Re: Revocation of EUA202965

Dear Dr. Platt:

This letter is in response to the request from Bio-Rad Laboratories, Inc., received via email on March 17, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA, with an effective date of April 15, 2022, for the Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit issued on February 11, 2021, and amended on September 23, 2021. Bio-Rad Laboratories, Inc. ceased U.S. distribution of the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit on March 2, 2022, and has discontinued this assay.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Bio-Rad Laboratories, Inc. has notified FDA that it has ceased U.S. distribution of the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit, has discontinued the assay, and requested FDA revoke the EUA for the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, per your request, effective April 15, 2022, FDA hereby revokes EUA202965 for the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit, pursuant to section 564(g)(2)(C) of the Act. Effective as of April 15, 2022, the Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

April 20, 2022

Clay D. Shorrock, Esq.
Chief Legal Officer and Exec. Dir., Business Development
Applied DNA Sciences, Inc.
50 Health Sciences Drive
Stony Brook, NY 11790
Re: Revocation of EUA200474

Dear Mr. Shorrock:

This letter is in response to the request from Applied DNA Sciences, Inc., received on April 7, 2022, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the Linea COVID-19 Assay Kit issued on May 13, 2020, re-issued on May 11, 2021, and amended on July 8, 2020, July 30, 2020, September 25, 2020, November 21, 2020, July 21, 2021, and September 23, 2021. Applied DNA Sciences, Inc. indicated that it is no longer distributing or utilizing the Linea COVID-19 Assay Kit. Applied DNA Sciences, Inc. has transitioned to the use of the Linea 2.0 COVID-19 Assay and other EUA-authorized tests.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Applied DNA Sciences, Inc. has notified FDA that it has decided to discontinue distribution of the Linea COVID-19 Assay Kit and requested FDA withdraw the EUA for the Linea COVID-19 Assay Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200474 for the Linea COVID-19 Assay Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Linea COVID-19 Assay Kit is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Cc: James A. Hayward, Ph.D., Chairman, President & CEO, Applied DNA Sciences, Inc.

Dated: May 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-09887 Filed: 5/6/2022 8:45 am; Publication Date: 5/9/2022]